Ofatumumab (Kesimpta®)	Place of Service Office Administration Outpatient Facility Infusion Administration Infusion Center Administration Self-Administration – *May be covered under the pharmacy benefit* HCPCS: J3590 NDCs • 0078-1007-68: 20 mg/0.4 mL single-dose prefilled Sensoready Pen • 0078-1007-68: 20 mg/0.4 mL single-dose prefilled syringe

Condition listed in policy *(see criteria for details)*

- Multiple sclerosis - relapsing to include clinically isolate syndrome, relapsing-remitting disease, and active secondary progressive disease in adults

AHFS therapeutic class: Immunomodulatory agent

Mechanism of action: Recombinant human IgG1 anti-CD20 monoclonal antibody

(1) Special Instructions and Pertinent Information

This drug is managed under the outpatient Pharmacy Benefit for self-administration. Please contact the member's Pharmacy Benefit for information on how to obtain this drug.

To submit a request to the Medical Benefit, please submit clinical information for prior authorization review and include medical rationale why the patient cannot self-administer this drug in the home.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Kesimpta® (ofatumumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Multiple sclerosis - relapsing to include clinically isolate syndrome, relapsing-remitting disease, and active secondary progressive disease in adults

1. Inadequate response, or intolerable side effect to two preferred MS disease-modifying agent (i.e. Extavia, Gilenya, dimethyl fumarate, or a glatiramer containing product), OR contraindication to all

   AND

2. Not being used in combination with another disease-modifying therapy for MS (e.g., Aubagio, Avonex, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Lemtrada, mitoxantrone, Ocrevus, Rebif, Tysabri, or Tecfidera)

Covered Dose
Up to 20 mg SC at Week 0, 1, 2, and 4, then monthly thereafter

Coverage Period
Indefinitely

ICD-10:

G35

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Kesimpta® (ofatumumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How Supplied:

- 20 mg/0.4 mL solution in a single-dose prefilled pen
- 20 mg/0.4 mL solution in a single-dose prefilled syringe

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Kesimpta® (ofatumumab) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 8/2020.
- Rae-grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2018;90(17):777-788.

(7) Policy Update

Date of last review: 4Q2022
Date of next review: 4Q2023
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee